



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2464]

Advancing the Development of Pediatric Therapeutics: Application of “Big Data” to Pediatric Safety Studies; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Office of Pediatric Therapeutics, Food and Drug Administration (FDA), is announcing a public workshop entitled “Advancing the Development of Pediatric Therapeutics (ADEPT): Application of “Big Data” to Pediatric Safety Studies.” The purpose of this 2-day workshop is to understand how to access and analyze “Big Data” associated with safety information in the health care setting, and the utility and challenges associated with the use of “Big Data” to study the safety of therapeutics in children.

DATES: The public workshop will be held on September 18 and 19, 2017, from 8:30 a.m. to 5 p.m. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public workshop will be held at the DoubleTree by Hilton Hotel, 8727 Colesville Rd. (Route 29), Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Renan A. Bonnel, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-8654, Fax: 301-847-8640, renan.bonnel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Large volumes of data in the context of the health care industry have the potential to provide additional information related to medication use, which may affect the benefit-risk assessment of medicines in general and pediatric medicines in particular. Since pediatric pharmacoepidemiologic studies tend to enroll fewer patients than adult studies, additional information may be needed to better understand the safety and efficacy of use of these drugs in children. “Big Data”, including forms of real world evidence that may involve large and complex data sets, may be particularly useful as a supplement to traditional studies. Supplementary information may include additional clinical trial data, registry data, and electronic health record information.

II. Topics for Discussion at the Public Workshop

In this workshop, FDA will gather information on the latest developments in “Big Data” from the perspective of a number of stakeholders and expand the conversation to include the utility and challenges associated with the use of “Big Data” in the pediatric setting. Day 1 will focus on national and international uses of “Big Data” in health care. Day 2 will focus on “Big Data” utility in the pediatric setting, including specific challenges associated with pediatric data.

III. Participation in the Public Workshop

Registration: Persons interested in attending this workshop must register online at: <https://www.eventbrite.com/e/public-workshop-advancing-the-development-of-pediatric-therapeutics-adept-application-of-big-data-tickets-32470264435> by August 22, 2017. For those without internet access, please contact Renan A. Bonnel (see FOR FURTHER INFORMATION CONTACT) to register.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by August 22, 2017. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants.

Registration information, the agenda, and additional background materials can be found at <https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm545847.htm>.

If you need special accommodations due to a disability, please contact Renan A. Bonnel (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance. Persons attending the meeting are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. September 18: Login URL: <https://event.webcasts.com/starthere.jsp?ei=1144352> (morning session).

After the morning session, users will be automatically redirected to the afternoon link. Should you lose connection over lunch, please use the following link for the afternoon session (Note: the link for the afternoon session is different from the morning session): Login URL: <https://event.webcasts.com/starthere.jsp?ei=1144354> (afternoon session).

September 19: Login URL: <https://event.webcasts.com/starthere.jsp?ei=1144356> (morning session).

After the morning session, users will be automatically redirected to the afternoon link. Should you lose connection over lunch, please use the following link for the afternoon session (Note: the link for the afternoon session is different from the morning session): Login URL: <https://event.webcasts.com/starthere.jsp?ei=1144357> (afternoon session).

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff office (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will be available on the internet at <https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm545847.htm>.

Dated: August 17, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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